24. The method of claim 16 wherein the amount of the mixtures of ibuprofen, isomers thereof, and pharmaceutically acceptable salts thereof is from about 100 to about 1700 milligrams per dose.

25. The method of claim 16 wherein the amount of the mixtures of ibuprofen, isomers thereof, and pharmaceutically acceptable salts thereof is from about 200 to about 1300 milligrams per dose.

26. A method for mitigating or treating photophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen as the sole anti-migraine agent.

27. A method for mitigating or treating phonophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen as the sole anti-migraine agent.

Please delete claims 27 – 30.

REMARKS

Reconsideration of the captioned application as amended herewith is respectfully requested.

The Office Action rejected claims 1 – 26 under 35 USC §102(f), as being anticipated by the Furey, et al. abstract ("Furey"), and rejected claims 1 – 26 under 35 USC §103(a) as being unpatentable over the Diener, et al. publication ("Diener") in view of United States Patent No.: 5,914,129 to Mauskop ("Mauskop").

During a telephone conference with Examiner Jagoe and the undersigned on 9 May 2002, Examiner Jagoe confirmed that Applicant's Preliminary Amendment mailed on 4 October 2001 ("Preliminary Amendment") was received in the Patent Office on 28 February 2002, which was one (1) day after the Office Action was mailed. For sake of clarity in the prosecution, Applicant requests entry of the Preliminary Amendment, which included new claims 27 to 30. Applicant further requests the cancellation of these claims 27 to 30 in this Amendment. Claims 1

– 26 are pending in this application after entry of this Amendment and the Preliminary Amendment.

The Rejection of Claims 1 – 26 Under
35 USC §102(f) Based on Furey Has Been Overcome.

Claims 1 – 26 stand rejected under 35 U.S.C. § 102(f) as being anticipated by Furey. Applicants respectfully disagree in view of the ensuing discussion.

Furey is an abstract of a paper that was presented at the 28th annual meeting of the ACCP on September 16 – 18, 1999 and published in volume 39(9) of the Journal of Clinical Pharmacology in its September, 1999 issue. Furey was received in the Information Center of McNeil-PPC, Inc., the assignee to the above-referenced application, on or about 24 August 1999, which is less than one (1) year before Applicant's United States priority filing date of 24 November 1999.

To the best of Applicant's knowledge, only the abstract of Furey has been published to date. However, Applicant wishes to bring the article cited in 20 Cephalalgia 233-43 (2000) regarding evaluation of ibuprofen for treatment of migraine headache to the Examiner's attention since Furey is listed as a coauthor to this publication. A copy of this article is included with the information disclosure statement filed concurrently herewith.

In the priority application, United States No. 09/449,124 (MCP 243), Applicant filed a declaration under 37 CFR 1.131 ("Declaration"), which demonstrated that Applicant had conceived and reduced to practice the claimed invention before August, 1999. In order to clarify a typographical error contained in the page number of the Furey reference as presented in the Declaration, Applicants have revised, updated, and reexecuted that Declaration. A copy of that Supplemental Declaration is attached hereto. In view of the attached Supplemental Declaration, Applicant respectfully submits that the rejection of claims 1 – 26 under 35 U.S.C. § 102(f) based on Furey has been overcome and should be withdrawn.

The Rejection of Claims 1 - 26
Under 35 USC §103 Based
on Diener in view of Mauskop Has Been Overcome.

Claims 1 - 26 stand rejected under 35 USC §103 as being allegedly unpatentable over Diener in view of Mauskop. Applicants respectfully disagree in view of the ensuing discussion.

Diener discloses that migraines are a disorder that includes various symptoms such as "headache, nausea, vomiting, photo-and phonophobia and malaise." Diener, page 811, abstract. Diener further discloses that "[a]spirin, ibuprofen, and paracetamol (acetaminophen)" are useful analgesics for treating mild to moderate migraine attacks. Diener, page 813, column 2, lines 3 – 5. However, as acknowledged in the Office Action, Diener fails to disclose or suggest that ibuprofen is useful in mitigating or treating photophobia or phonophobia associated with a migraine as claimed herein.

Mauskop teaches the use of a composition consisting essentially of: 1) an analgesic agent; 2) a magnesium salt; and 3) a stimulant for the alleviation of migraine symptoms such as photophobia and phonophobia. See Mauskop, Abstract. Ibuprofen is included as one of many possible analgesic compounds. See Mauskop, column 2, line 62 – claim 3, line 18. However, Mauskop expressly provides that "the combination of a magnesium salt and the analgesic agent(s) exert(s) a synergistic effect for relieving pain and related migraine symptoms." Mauskop, column 3, lines 23 – 26.

Mauskop neither discloses or suggests the use of "ibuprofen, isomers thereof, or mixtures thereof" as the "sole anti-migraine agents" for the treatment or mitigation of photophobia or phonophobia as claimed herein. Further, Mauskop neither discloses or suggests the use of "ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole anti-migraine agents, [for the treatment or mitigation of photophobia or phonophobia] wherein the pharmaceutically acceptable salt of ibuprofen is :

a) an inorganic cation salt selected from sodium, potassium, lithium, calcium, cesium, ammonia, ferrous, zinc, manganous, aluminum, ferric, and manganic;

b) an organic salt of ibuprofen with primary, secondary, tertiary and quaternary amines selected from triethylamine, tripropylamine, 2-dimethylaminoethanol, 2-diethylaminoethanol, lysine, arginine, histidine, caffeine, procain, N-ethylpiperidine, hydrabamine, choline, betaine, ethylenediamine, glucosamine, TRIS(hydroxymethyl)aminomethane, methylglycamine, theobromine, pruines, piperazine, piperidine, and polyamine resins; or

c) mixtures thereof,"

as claimed herein. In view of the fact that the cited references, either alone or in combination, fail to disclose or suggest the treatment or mitigation of photophobia and phonophobia via use of the claimed ibuprofen, ibuprofen isomer, and pharmaceutically accetpable salts of ibuprofen, as the "sole anti-migraine agents," Applicants respectfully submit that the rejection of claims 1 – 26

under 35 USC §103 as being unpatentable over Diener in view of Mauskop has been overcome and should be withdrawn.

Conclusion

It is submitted that the foregoing amendments and remarks place the case in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The following claims were amended:

IN THE CLAIMS:

1. (Amended) A method for mitigating or treating photophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen [, pharmaceutically acceptable salts thereof,] isomers thereof, or mixtures thereof, as the sole [pharmaceutically effective ingredients] anti-migraine agents .

4. (Amended) A method for mitigating or treating phonophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, [pharmaceutically acceptable salts thereof,] isomers thereof, or mixtures thereof, as the sole [pharmaceutically active ingredients] anti-migraine agents.

7. (Amended) The method of claim 1 wherein the amount of ibuprofen, [pharmaceutically acceptable salts thereof,] isomers thereof, or mixtures thereof, is about 200 milligrams per dose.

8. (Amended) The method of claim 1 wherein the amount of ibuprofen, [pharmaceutically acceptable salts thereof,] isomers thereof, or mixtures thereof, is about 400 milligrams per dose.

9. (Amended) The method of claim 4 wherein the amount of ibuprofen, [pharmaceutically acceptable salts thereof,] isomers thereof, or mixtures thereof, is about 200 milligrams per dose.

10. (Amended) The method of claim 4 wherein the amount of ibuprofen, [pharmaceutically acceptable salts thereof,] isomers thereof, or mixtures thereof, is about 400 milligrams per dose.

11. (Amended) A method for mitigating or treating photophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole anti-migraine agents,

[The method of claim 1] wherein the pharmaceutically acceptable salts of ibuprofen are selected from the group consisting of [:

a) inorganic cation salts;

b)] organic salts of ibuprofen with pharmaceutically acceptable primary, secondary, tertiary, and quaternary amines [; and

c) mixtures thereof].

12. (Amended) A method for mitigating or treating photophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole anti-migraine agents, [The method of claim 1] wherein the pharmaceutically acceptable salt of ibuprofen is :

a) an inorganic cation salt selected from sodium, potassium, lithium, [magnesium,] calcium, cesium, ammonia, ferrous, zinc, manganous, aluminum, ferric, and manganic;

b) an organic salt of ibuprofen with primary, secondary, tertiary and quaternary amines selected from triethylamine, tripropylamine, 2-dimethylaminoethanol, 2-diethylaminoethanol, lysine, arginine, histidine, caffeine, procain, N-ethylpiperidine, hydrabamine, choline, betaine, ethylenediamine, glucosamine, TRIS(hydroxymethyl)aminomethane, methylglycamine, theobromine, pruines, piperazine, piperidine, and polyamine resins; or

c) mixtures thereof.

13. (Amended) A method for mitigating or treating photophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole anti-migraine agents, [The method of claim 1] wherein the mixture is a mixture of ibuprofen and its potassium salt.

15. (Amended) [The method of claim 4] A method for mitigating or treating phonophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole [pharmaceutically active ingredients] anti-migraine agent,

wherein the pharmaceutically acceptable salts of ibuprofen are selected from the group consisting of [:

a) inorganic cation salts;

b)] organic salts of ibuprofen with pharmaceutically acceptable primary, secondary, tertiary, and quaternary amines [; and

c) mixtures thereof] .

16. (Amended) A method for mitigating or treating phonophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole [pharmaceutically active ingredients] anti-migraine agent,

[The method of claim 4] wherein the pharmaceutically acceptable salt of ibuprofen is :

a) an inorganic cation salt selected from sodium, potassium, lithium, [magnesium,] calcium, cesium, ammonia, ferrous, zinc, manganous, aluminum, ferric, and manganic;

b) an organic salt of ibuprofen with primary, secondary, tertiary and quaternary amines selected from triethylamine, tripropylamine, 2-dimethylaminoethanol, 2-diethylaminoethanol, lysine, arginine, histidine, caffeine, procain, N-ethylpiperidine, hydrabamine, choline, betaine, ethylenediamine, glucosamine, TRIS(hydroxymethyl)aminomethane, methylglycamine, theobromine, pruines, piperazine, piperidine, and polyamine resins; or

c) mixtures thereof.

17. (Amended) A method for mitigating or treating phonophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen, pharmaceutically acceptable salts thereof, isomers thereof, or mixtures thereof, as the sole anti-migraine agent,

[The method of claim 4] wherein the mixture is a mixture of ibuprofen and its potassium salt.

19. (Amended) The method of claim 12 wherein the amount of the pharmaceutically acceptable salts of ibuprofen is from about 100 to about 1700 milligrams per dose.

20. (Amended) The method of claim [4] 16 wherein the amount of the pharmaceutically acceptable salts of ibuprofen is from about 100 to about 1700 milligrams per dose.

21. (Amended) The method of claim 12 wherein the amount of the mixtures of ibuprofen, [isomeres] isomers thereof, and pharmaceutically acceptable salts thereof is from about 100 to about 1700 milligrams per dose.

22. (Amended) The method of claim 12 wherein the amount of the mixtures of ibuprofen, [isomeres] isomers thereof, and pharmaceutically acceptable salts thereof is from about 200 to about 1300 milligrams per dose.

23. (Amended) The method of claim [4] 16 wherein the amount of the mixtures of ibuprofen, isomers thereof, and pharmaceutically acceptable salts thereof is from about 100 to about 1700 milligrams per dose.

24. (Amended) The method of claim [4] 16 wherein the amount of the mixtures of ibuprofen, isomers thereof, and pharmaceutically acceptable salts thereof is from about 200 to about 1300 milligrams per dose.

25. (Amended) A method for mitigating or treating photophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen as the sole [pharmaceutically effective ingredient] anti-migraine agent.

26. (Amended) A method for mitigating or treating phonophobia associated with migraine to a patient in need thereof comprising:

providing an effective amount of ibuprofen as the sole [pharmaceutically effective ingredient] anti-migraine agent.

Claims 27 – 30 were deleted.

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